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Statement of Rep. Christopher Shays
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Work by this Subcommittee provided critical impetus for passage of the Persian Gulf War Veterans Act of 1998. That law directs the Department of Veterans Affairs (VA) to seek independent assessments of possible associations between toxic exposures and the unusual syndromes afflicting many ill veterans. If a scientifically valid association is found, the VA may by regulation establish a presumption of service-connection in favor of those applying for health and disability benefits.

That process was intended to allow the VA to give sick veterans the benefit of the doubt until hard evidence of causality between wartime exposures and chronic illnesses emerges from ongoing research. In the meantime, the law directs the VA to look to studies on animals to fill gaps in clinical and epidemiological data.

Last year, a VA-sponsored review by the Institute of Medicine (IOM) on the effects of low-dose sarin exposure raised questions whether the statutory mandate to use animal data is being followed. Former VA Secretary Anthony Principi specifically requested a reappraisal of earlier conclusions on sarin exposure based on the emergence of significant new studies showing chronic brain function changes in animals after low-dose exposures. But the IOM committee reported animal studies played only a small role in their assessment. Not surprisingly, the expert committee, as before, found no connection between sub-clinical sarin exposures and human illnesses.

That conclusion epitomized what many veterans see as a deeply entrenched reluctance in the VA and allied medical institutions to extrapolate from animal data on fundamental questions of disease causation. As the VA sees it, toxicology studies on rats and other animal data may be useful to probe the biological plausibility of a medical hypothesis; but only data from studies involving humans can be relied upon to determine a legitimate association between exposure and human disease.

That sustained unwillingness to rely on animal studies thwarts a fundamental purpose of the statute: to ease the traditional burden of proof borne by veterans claiming service-connected injury and disability. Whether motivated by a lack of scientific vision or a fear of fiscal implications, the refusal to give greater sway to animal data in Persian Gulf War Veterans Act determinations undercuts the basic intent of the law to expand the scope of evidence upon which VA may connect today's mysterious illnesses to wartime service a decade and a half ago.

Those at the VA charged with implementing the statute have to know the gold standard of human data on sarin exposure they demand may never be available. Gulf War veterans don't know the dose to which they were exposed, and their fate should not hinge on the unthinkable prospect we'll have more veterans or terrorism victims to study. In terms of research protocols, it is unethical to intentionally expose human test subjects to lethal agents. So only data from animal studies will allow VA to construct the links between exposure and ailments that sick veterans cannot. But, as we will hear from close observers of the process today, it appears VA has repeatedly attempted to minimize the role and impact of animal data in Gulf War studies.

Ironically, another major scientific organization is moving in exactly the opposite direction. The Food and Drug Administration's Animal Efficacy Rule allows for approval of certain new drugs and biological products based solely on data from animal studies. So the experimental drugs and vaccines soldiers might be ordered to take against bioterrorism agents can be approved through unprecedented reliance on animal data, but determinations regarding the toxic causes of their subsequent illnesses still cannot.

Our witnesses all bring extraordinary commitment to the cause of helping veterans, and we appreciate their time and expertise as the Subcommittee continues to pursue these difficult issues.